

FDA Reminder: Safe Use of Non-Sterile Alcohol Prep Pads (3/11)

The US Food and Drug Administration (FDA) recently posted information about the safe use of non-sterile alcohol prep pads used to clean and disinfect skin surfaces. This was the result of a recent recall of potentially contaminated non-sterile alcohol prep pads issued by Triad Group of Hartland, Wisconsin (see below).



The FDA reminds health-care professionals that "Non-sterile pads are not intended to prep patients prior to procedures requiring strict sterility measures and should not be used on patients with a depressed immune system, to prep patients for catheter insertion, or to prep patients prior to surgery." Sometimes manufacturers may package a prep pad with an injectable drug, selling them as a kit. But not all marketed pads are sterile. Some are marketed as non-sterile alcohol pads. If a pad does not state "sterile" on the label, health-care professionals should be aware that they are using a non-sterile pad.

Recall Information

Watson Pharmaceuticals, Inc. recently announced a recall involving ALL LOTS of Alcohol Prep Pads, Alcohol Swabs or Alcohol Swabsticks manufactured by Triad Group. Triad Group is recalling the alcohol prep pads packaged with products, including Watson's Trelstar® (triptorelin pamoate for injectable suspension) product, due to potential contamination of the pads with the bacteria, *Bacillus cereus*, which could result in life-threatening infections, especially in at-risk populations, including immune suppressed and surgical patients. This recall involves those products marked as STERILE as well as NON-STERILE products.

Use of contaminated Alcohol Prep Pads, Alcohol Swabs or Alcohol Swabsticks could lead to life-threatening infections, especially in at risk populations, including immune suppressed and surgical patients. To date one report of a **non**-life-threatening skin infection has been reported.

Alcohol Prep Pads, Alcohol Swabs and Alcohol Swabsticks are used to disinfect before an injection. They were distributed nationwide (United States, Canada, and Europe) to retail pharmacies and are packaged in individual packets and sold in retail pharmacies in a box of 100 packets. The affected Alcohol Prep Pads, Alcohol Swabs and Alcohol Swabsticks can be identified by either "Triad Group," listed as the manufacturer, or the products are manufactured for a third party and use the names listed below in their packaging:

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|-------------------|----------------|-----------------|-------------|
| - Cardinal Health | - VersaPro | - Moore Medical | - CVS |
| - PSS Select | - Boca/Ultilet | - Walgreens | - Conzellan |

Customers distributing the product and selling it at the wholesale, hospital and retail pharmacy level have been reportedly notified by certified mail with instructions on how to return the product. If a consumer has any of these types of products in their possession listing "Triad Group" as the manufacturer, they should not use the product and should return it to the place it was purchased for a full refund or call Triad Group Customer Service at (262) 538-2900. The Triad Group will issue you a return authorization number and make all return arrangements.

Additional information is available on the FDA Web site by visiting:

www.fda.gov/Safety/Recalls/ucm242359.htm or
www.fda.gov/NewsEvents/Newsroom/PressAnnouncements/ucm241750.htm.